

PND22

QUANTIFYING COST OUTCOMES DIFFERENTIATED BY GENDER AND AGE IN THE TREATMENT OF MIGRAINE HEADACHE USING STEP AND STRATIFIED CARE

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OBJECTIVES: The objective of this study was to estimate the cost savings of STEP vs. Stratified (STRAT) migraine headache care differentiated by age and gender. **METHODS:** Migraine headaches are a prevalent disorder resulting direct costs of \$2,571 per person per year on average which includes hospital visits and prescription drug costs. The indirect costs of migraine headaches are estimated to be about \$13 billion a year indirectly affecting the workplace through an estimated \$8 billion due to missed work days alone. A Monte Carlo microsimulation based upon previously published non-U.S. models was developed to evaluate the cost-benefit of stratified care based on MIDAS scores vs. the more commonly applied step care. Although STEP care delays the initiation of triptan therapy which is generally more costly and potentially habit forming, there may be cost-benefit from evaluating patient history and disease severity through MIDAS scores and advancing patients to more advanced therapies in severe cases. **RESULTS:** As expected, the greatest cost differences when adopting STRAT was for MIDAS III women age 40-49 due to the peak prevalence at this age/gender (STRAT vs. STEP = \$547 vs. \$1,572 per case) with similar trend found for males of the same age (\$515 vs. \$1,464). However, the cost differences for STRAT vs. STEP care for aged 60+ was significant (\$136 vs. \$326) and the difference for patients (age 12-17) was \$199. Adoption of STRAT care in routine clinical practice yields differences of \$1,025 and \$949 per patient per year for females and males respectively. Further evidence shows that cost differences for those ages 60+ were \$190, and those under age 30 were \$199. **CONCLUSIONS:** Although the differences for the latter two age strata were smaller, they may have implications for specialized populations such as Medicare and Medicaid and the impact they have on plan budgets.

PND23

ECONOMIC EVALUATION OF DEXMEDETOMIDINE FOR SEDATION IN THE INTENSIVE CARE UNIT

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OBJECTIVES: Dexmedetomidine is an alpha-2 receptor agonist used in continuous infusion for the sedation of critically ill patients in intensive care unit who are intubated and mechanically ventilated. Compared to midazolam in the sedation of intensive care unit patients, dexmedetomidine showed a decrease in time spent on ventilator, fewer episodes of delirium and reduced incidence of tachycardia and hypertension. The aim of this study was to assess the economic impact, in a Canadian context, of dexmedetomidine for sedation in intensive unit care compare with midazolam, a GABA agonist. **METHODS:** This economic evaluation was performed using a cost-consequences analysis, according the perspective of Canadian Health Care system. The time horizon chosen is an intensive care unit stay with a maximum length of 30 days. Clinical data were obtained from a prospective randomized, double-blinded trial by Riker and al. comparing dexmedetomidine and midazolam. Costs considered in this evaluation were those of the medications, of the mechanical ventilation, of the delirium episodes, and those associated with adverse events requiring an intervention. All costs were adjusted to 2010 and were reported in Canadian dollars. **RESULTS:** The average cost of medication was higher with dexmedetomidine (\$1,930) than with midazolam (\$180), but the average cost associated with mechanical ventilation and with the management of delirium were lower with dexmedetomidine (\$2,939 and \$3,630 respectively) than with midazolam (\$4,448 and \$5,149). Overall cost per patient with dexmedetomidine (\$8,525) was lower than with midazolam (\$9,817). Deterministic sensitivity analysis confirmed the robustness of this difference. **CONCLUSIONS:** The results of this cost-consequences analysis indicated that the use of dexmedetomidine is a favorable strategy in terms of clinical consequences and economic impact compare to midazolam. Compared to midazolam, dexmedetomidine is a less expensive strategy associated with a lower occurrence of delirium and a shorter duration of mechanical ventilation.

PND24

QUALITY OF LIFE USING TREATMENTS FOR PARKINSON'S DISEASE: AN ECONOMIC COMPARISON BETWEEN ROPINIROLE AND LEVODOPA/CARBIDOPA

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OBJECTIVES: Parkinson's disease (PD) is the second common neuro-degenerative disease in US older adults. Until recently, Levodopa was the only treatment for PD. Although, Ropinirole is approved by FDA for PD, there are no cost-effectiveness studies comparing these treatments. The objective of our study is to perform cost-effectiveness analysis comparing Ropinirole and the combination therapy of Levodopa/Carbidopa in the treatment of PD. **METHODS:** A cost-effectiveness analysis was performed from the patient's perspective to compare Ropinirole and Levodopa/Carbidopa treatment in PD patients using a decision tree model as a pragmatic tool to derive comparative information on the costs and effectiveness of these two strategies over a 5-year period. A predictive model was developed to capture utilization, such as medication (drug) costs, physician costs, caregiver time, and productivity loss. Clinical information was derived from a comparative effectiveness study. All direct and indirect costs were obtained from pharmacists, published literature, and medical practitioners. Effectiveness was measured in terms of quality adjusted life years (QALY) reported in literature. Costs were adjusted to

2009 U.S. dollars. One way and two way sensitivity analyses with 25% change in cost and 20% change in QALY values were performed and incremental cost effectiveness ratio (ICER) was calculated. **RESULTS:** The Ropinirole therapy resulted in a gain of 2.82 QALY's at a cost of \$107,062 compared to Levodopa/Carbidopa combination therapy which resulted in a gain of 2.35 QALY's at a cost of \$102,423 at the end of 5 years. The expected cost per QALY was \$37,965 for Ropinirole while that of Levodopa/Carbidopa combination was \$43,584. One way and two way analyses were consistent, validating the results. ICER was found to be \$9,870 per QALY for switching from Ropinirole to Levodopa/Carbidopa therapy. **CONCLUSIONS:** Our cost-effectiveness analysis indicates that Ropinirole is a better option as compared to Levodopa/Carbidopa for treatment of patient suffering from PD.

PND25

ECONOMIC TRENDS ASSOCIATED WITH NATALIZUMAB THERAPY IN A COMMERCIALY MANAGED MULTIPLE SCLEROSIS POPULATION

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OBJECTIVES: Identify a population of multiple sclerosis (MS) patients new to treatment with natalizumab. Observe and record healthcare costs before initiation of natalizumab and up to 3 years after continuing treatment. Compare and quantify differences in costs based on patterns of natalizumab use. **METHODS:** Using integrated medical and pharmacy claims data (IMS LifeLink™ Health Plan Claims and Longitudinal Prescriptions databases), patients were included in the analysis based on the presence of a diagnosis of MS (ICD-9 code 340.*) during calendar years 2005 through 2008. Economic information related to the treatment of MS was captured using the Episode Treatment Group™ software. **RESULTS:** From the database, 76 MS patients that started natalizumab treatment and had 4 full calendar years of data were observed. These patients were observed for the year prior to start of natalizumab treatment in 2006, through the end of the 2008 calendar year. Patients were stratified by continued use of natalizumab during the study period. For all patients, there were significant increases in annual pharmacy costs (\$17,667 to \$40,399) during the year natalizumab treatment was initiated, in addition to outpatient medical services (\$8,383 to \$11,744). For patients who continued natalizumab for the entire study period, inpatient costs decreased from \$2,630 to an average of \$5 per year; emergency room costs in this group also decreased from a maximum of \$537 to \$218 annually. For patients who discontinued natalizumab during the study period, there were increased inpatient costs after discontinuation (\$2,630 to \$6,701). **CONCLUSIONS:** Though the study size is small, the cost observations can enable decision-makers to better understand costs associated with the short and longer-term use of natalizumab for the treatment of MS.

PND26

MEASURING THE IMPACT OF NATALIZUMAB THERAPY ON HEALTH CARE UTILIZATION IN A COMMERCIALY MANAGED MULTIPLE SCLEROSIS POPULATION

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OBJECTIVES: Identify a population of MS patients new to treatment with natalizumab. Observe and record healthcare utilization before initiation of natalizumab and up to 1 year after continuing treatment. Compare and quantify differences in healthcare utilization for the period prior to natalizumab treatment through the following calendar year. **METHODS:** Using integrated medical and pharmacy claims data (IMS LifeLink™ Health Plan Claims and Longitudinal Prescriptions databases), patients were included in the analysis based on the presence of a diagnosis of MS (ICD-9 code 340.*) during calendar years 2006 through 2008. Clinical and utilization information related to the treatment of MS were captured using the Episode Treatment Group™ (ETG™) episode-building software. **RESULTS:** From the database, 349 MS patients that were both new to natalizumab treatment in 2007 and had 3 full calendar years of data were observed. In the year of treatment initiation with natalizumab, there was an overall increase in the number of prescriptions received (14.0 to 22.6 per year), as well outpatient medical services (16.1 to 25.6) which would be expected with starting a new MS therapy. In addition to these increases, ER and inpatient utilization were also on the rise prior to initiation of natalizumab, however, utilization of ER and inpatient services significantly decreased in the following calendar year. During this period, there were also significant decreases in the amount of drugs used for supportive care of MS including corticosteroids, antispastic agents, and benzodiazepines. **CONCLUSIONS:** Healthcare costs were at their highest in the year natalizumab was initiated. Following initiation of natalizumab therapy, there was a decrease in ER, inpatient and supportive care utilization.

PND27

MEDICO-ECONOMIC EVALUATION OF LACOSAMIDE ADJUNCTIVE THERAPY IN THE TREATMENT OF PATIENTS WITH REFRACTORY EPILEPSY IN THE UNITED STATES

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OBJECTIVES: To calculate and compare the incremental cost-utility ratios for standard antiepileptic drug (AED) therapy with and without adjunctive lacosamide in patients with uncontrolled partial-onset seizures. **METHODS:** The model simulated the treatment pathway of a hypothetical cohort of 1000 patients over two years from the third party payer perspective in the United States in 2010. A decision tree was split into four phases of six months each during which patients can become seizure free, experience a seizure reduction (responder defined as ≥50% reduction in seizures), or withdraw due to non-response. The standard therapy arm included five adjunctive therapies: carbamazepine, lamotrigine, levetiracetam, topiramate, and valproate. The likelihood of being in a particular health state

has been estimated from clinical trials data. The cost of general practitioner visits, specialist visits, hospitalizations and emergency department visits were included. Costs and utility values attached to various health states were taken from the published literature. **RESULTS:** Lacosamide adjunctive therapy was associated with 6,730 avoided seizures and a gain of 38 quality adjusted life-years (QALYs), compared to the standard therapy arm within the two-year timeframe. Treatment with lacosamide was associated with a cost of \$223 per seizure avoided, and \$39,574 per QALY gained versus standard therapy over two years and falls within acceptable thresholds of cost-effectiveness in the United States. Results calculated for 6-, 12- and 18-month follow-up showed respective incremental cost-utility ratios of \$55,465, \$46,587 and \$44,559 and cost per seizure avoided of \$733, \$305 and \$260. Using a willingness-to-pay threshold of \$50,000 per QALY, 77% of the simulations fell below this value after 2 years of treatment. **CONCLUSIONS:** Lacosamide was shown to be a cost-effective adjunctive treatment in patients with uncontrolled partial-onset epilepsy in the United States.

Neurological Disorders – Patient-Reported Outcomes & Preference-Based Studies

PND28

THE RELATIONSHIP BETWEEN ALTERNATIVE MEDICATION POSSESSION RATIO THRESHOLDS AND OUTCOMES: EVIDENCE FROM THE USE OF GLATIRAMER ACETATE

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OBJECTIVES: Examine how changes in the medication possession ratio (MPR) affect patient outcomes among multiple sclerosis (MS) patients treated with glatiramer acetate (GA; Copaxone®). **METHODS:** Data were obtained from i3 InVision Data Mart for January 1, 2006 – March 31, 2010. Patients were included if they were diagnosed with MS, initiated therapy with GA, and had continuous insurance coverage from 6 months prior through 24 months post initial use of GA (N=839). Multivariate regressions which controlled for patient characteristics examined the association between achievement of alternative MPR goals and patient relapses and charges. Logistic regressions were used to examine the relapses, while generalized linear models were used to examine charges. **RESULTS:** Patients who achieved an MPR of at least 0.7 had significantly lower odds of relapse, with achievement of a threshold of 0.7, 0.8 or 0.9, respectively, associated with an odds ratio of relapse of 0.545 (95% CI 0.351 – 0.824), 0.530 (95% CI 0.371 – 0.870), and 0.421 (95% CI 0.260 – 0.679). Larger reductions in total direct medical charges, excluding drugs, were seen with higher MPR thresholds. For example, achievement of an MPR threshold of at least 0.5 was associated with \$1524 lower total charges (P=0.0034), while a MPR threshold of 0.90 was associated with \$1825 lower charges (P=0.0005). Examining MS-related total charges, exclusive of drugs, revealed that a MPR threshold of 0.90 was associated with \$986 lower total MS-related charges (P=0.0498). Results also found an association between patient adherence to GA and statistically significant reduction in inpatient, ER, outpatient, MS-related inpatient and MS-related outpatient charges. **CONCLUSIONS:** As adherence improves the odds of relapse decreases and cost-savings, exclusive of drugs, generally increase. Results suggest that, despite the higher costs associated with increased usage of GA, patient outcomes are improved and there are cost-offsets associated with “compliant” use of the medication.

PND29

VALIDATION OF THE HUNTINGTON CLINICAL SELF-REPORTED INSTRUMENT (H-CSRI), A CLINIMETRIC PATIENT ASSESSED SCALE FOR PATIENTS WITH HUNTINGTON'S DISEASE

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OBJECTIVES: Huntington's disease (HD) is a rare neurodegenerative disease affecting motor, cognitive and psychological function. Data collection is difficult because of the low prevalence and the small number of specialized centers. The creation of a specific self-administered questionnaire covering various clinical aspects of the disease would make the HD-patient clinical data collection easier. Such an instrument also offers the advantage of allowing a remote follow-up and getting information on the development of motor, functional and behavioral disorders of HD patients perceived by the patient himself. The objective of this study is to validate a new self-reported clinical instrument for HD-patients. **METHODS:** The European HD burden study (Euro-HDB) is an ongoing cross-sectional survey among HD-patients and their caregivers in six European countries. The H-CSRI, a self-reported instrument based on the Unified Huntington's Disease Rating Scale (UHDRS) and developed with the expertise of a neurologist and a psychiatrist, was administered. It included three subscales assessing the motor, functional and behavioural ability. Classical test theory and item response theory were used to assess its clinimetric properties. **RESULTS:** Among 311 patients from both Italy and France, item response rates range from 86% to 99%. There was a floor effect on items related to psychotic disorder in the behavioral subscale, because these symptoms do not affect all patients. The H-CSRI showed an acceptable reliability (Cronbach's alphas > 0.74). Factor analyses demonstrated a satisfactory construct validity. Moreover, the item internal consistency and item discriminant validity criteria were met. The differential item functioning analyses showed no item bias between the two countries and between genders. **CONCLUSIONS:** These data support the validity of the H-CSRI to assess the health status for patients with HD. Planned next steps include assessments of responsiveness to change, test-retest reliability and convergence between UHDRS and H-CSRI scales.

PND30

QUALITY OF LIFE AMONG PATIENTS SUFFERING FROM MIGRAINE: HEALTH UTILITY BY FREQUENCY OF HEADACHE DAYS

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OBJECTIVES: Migraine in some patients may be progressive, with increasing headache day frequency leading to Chronic Migraine (CM). The relationship between headache-days per month (HDPm) and health utility, a measure of health-related quality of life (HRQoL), among patients with migraine has not been examined. **METHODS:** The PREEMPT trials studied 1,384 patients with CM treated with BOTOX® or placebo. The PREEMPT trials included migraine specific measures. No instrument to directly capture health utility, however, was included. Therefore, a validated mapping algorithm using patient characteristics, the Migraine Specific Questionnaire v.2 (MSQ), and the EuroQoL-5D (EQ-5D, UK weighted) was applied to the PREEMPT dataset in order to estimate mean health utility by health state, defined as 0-3, 4-9, 10-14, 15-19, 20-23, or ≥24 HDPm. Analyses were performed both regardless of treatment and stratified by treatment arm. Health utility is a standard scale to measure HRQoL, ranging from 1, representing perfect health, to 0, representing death. **RESULTS:** PREEMPT patients were predominantly female (86%) and Caucasian (90%), with a mean age of 41. At week 24, mean health utility for each of the HDPm categories was 0.75 (0-3 HDPm), 0.68 (4-9 HDPm), 0.62 (10-14 HDPm), 0.53 (15-19 HDPm), 0.53 (20-23 HDPm), and 0.52 (24+ HDPm). A similar trend of decreasing utility with increasing HDPm was observed at baseline, week 12, and week 56 and when stratified by treatment arm. **CONCLUSIONS:** An inverse relationship is seen between health utility and HDPm, with the headache frequency categories comprising CM (15-19, 20-23, and 24+ HDPm) associated with the lowest HRQoL. Health utility defined by HDPm categories will be valuable for estimating HRQoL gains as a result of migraine treatments which aim to reduce the number of HDPm among those suffering from migraine.

PND31

HEADACHE DAY HEALTH STATES AND TRANSITION PROBABILITIES FOR PATIENTS WITH CHRONIC MIGRAINE WITH AND WITHOUT HEADACHE PROPHYLAXIS

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OBJECTIVES: Chronic migraine is an undertreated and debilitating disease associated with significant morbidity. This research seeks to define meaningful health states based on published literature and where necessary, expert opinion. Health states defined by the number of headache-days per month (28 days; HDPm) experienced by patients with chronic migraine (≥15 headache days per month) can be used to calculate transition probabilities that may be applied to cost-effectiveness modeling. **METHODS:** Published literature, headache treatment guidelines, health utility, and health resource utilization, as well as the baseline distribution of HDPm in the pooled Phase 3 REsearch Evaluating Migraine Prophylaxis Therapy (PREEMPT) clinical trial program were considered to ascertain relevant HDPm to define migraine health states. Subsequently, pooled trial data were used to estimate transitions between health states per 12-week treatment cycle for patients treated with BOTOX® or placebo. Up to 24 weeks of double-blind data is available from the PREEMPT phase 3 trials, with an additional 32 weeks of open-label data for BOTOX® treated patients. All available data from the PREEMPT trials were used to model transitions. A Bayesian approach with a Dirichlet distribution was used to perform sensitivity analyses of these health state transitions. **RESULTS:** We specified 6 unique health states, defined by number of HDPm: 0-3, 4-9, 10-14, 15-19, 20-23, and 24+. The pooled trial cohort of 1384 patients (857 with prior prophylaxis failure) were examined at baseline, week 12 and week 24 to produce transition probabilities for both all patients and those with prior prophylactic failure. Estimated transition probabilities modeled to one year time horizon produce distributions that closely replicate the 56-week distribution of the PREEMPT trial population. **CONCLUSIONS:** This research generated unique migraine health states to form the foundation of cost-effectiveness models evaluating migraine therapies.

PND32

HEALTH RESOURCE UTILIZATION AND COSTS FOR MIGRAINEURS IN SCOTLAND

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OBJECTIVES: Migraine is a debilitating disease with significant morbidity. This research estimates the health resource utilization and associated cost of adult Scottish migraineurs within 6 distinct health states, defined by number of headache-days per month (28 days; HDPm), ranging from zero to 28, to inform a cost-effectiveness analysis of prophylaxis of headache in patients with chronic migraine (≥15 HDPm). **METHODS:** Standard cost of illness methods were used to combine unit costs for physician office visits, inpatient and emergency room encounters for migraine, and triptan medication use. Resource utilization data was taken from the International Burden of Migraine Study. Costs were derived from the NHS 2008/09 reference costs for England, and from the Personal Social Services Research Unit (PSSRU) costs. Total costs for each health state were estimated over a three month time interval. **RESULTS:** Resource utilization increased across all categories as the number of HDPm increased. Costs per 3 months ranged from £35.05 for the 0-3 headache-days health state to £226.14 for the 15+ HDPm health state. The largest cost driver among the 15+ HDPm was hospitalization for migraine, which accounted for 52% of costs in 15+ HDPm health state.